

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/337,746 06/22/99 GLENN

G PM-254811

EXAMINER

HM12/0810

PILLSBURY MADISON & SUTRO LLP
INTELLECTUAL PROPERTY GROUP
1100 NEW YORK AVENUE NW
NINTH FLOOR EAST TOWER
WASHINGTON DC 20005-3918

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

08/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/337,746

Applicant(s)

Glenn et al.

Examiner

G. R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 1, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 16) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 17) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald Ewoldt, Art Unit 1644, Technology Center 1600.

2. Applicant's election of Group I, Claims 1-42, 45, and 47-69, and the species *E. coli* enterotoxin, in Paper No. 15, filed 6/01/01, is acknowledged. However, upon further consideration a new restriction election is required. The previous restriction requirement and election are therefore vacated. A new restriction follows. The Examiner apologizes for any delay or inconvenience to the Applicant.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-29, 33-38, 40-42, and 53-69, drawn to a method for transcutaneous immunization to a bacterial antigen, classified in Class 424, subclasses 234.1, 278.1 and 283.1.

II. Claims 1-28, 30, 33-38, 41-42, and 56-69, drawn to a method for transcutaneous immunization to a viral antigen, classified in Class 424, subclasses 204.1, 278.1 and 283.1.

III. Claims 1-28, 31, 33-38, 41-42, and 57-69, drawn to a method for transcutaneous immunization to a fungal antigen, classified in Class 424, subclasses 278.1 and 283.1.

IV. Claims 1-28, 32-38, 41-42, and 57-69, drawn to a method for transcutaneous immunization to a parasite, classified in Class 424, subclasses 265.1, 278.1 and 283.1.

V. Claims 1 and 43-44, drawn to a method for transcutaneous immunization to an antigen encoded by a nucleic acid, classified in Class 424, subclasses 278.1 and 283.1 and Class 514, subclass 44.

VI. Claims 1 and 45-47, drawn to a method for transcutaneous immunization to an autoantigen, classified in Class 424, subclasses 278.1 and 283.1.

VII. Claims 1 and 48-50, drawn to a method for transcutaneous immunization to a tumor antigen, classified in Class 424, subclasses 277.1, 278.1 and 283.1.

VIII. Claims 1 and 51, drawn to a method for transcutaneous immunization to an allergen, classified in Class 424, subclasses 275.1, 278.1 and 283.1.

The inventions are distinct, each from the other because:

4. Inventions I-VIII are different methods. These inventions act through different process steps, with different modes of operation, different endpoints, and/or different outcomes. Note that there are significant differences between the immune responses to pathogenic antigens such as bacterial and viral antigens versus the immune response to endogenous tumor antigens or to autoantigens. Even among the pathogenic antigens, the response to a bacterial antigen is usually humoral, i.e., Th2 mediated, while the response to a viral antigen is usually cellular, i.e., Th1 mediated. Said responses comprise significantly different fields of search. Therefore they are patentably distinct.

5. Because these inventions are distinct for the reasons given above and Groups I-VIII have acquired a separate status in the art as shown by their different classification and/or the searches are not co-extensive and because the Groups encompass divergent subject matter, restriction for examination purposes as indicated is proper.

6. Should Applicant elect any of Groups I-V, Applicant is further required under 35 U.S.C. § 121 to elect:

A) a **specific** antigen or pathogenic organism, such as one listed on pages 28-32,

B) a **specific** molecular weight, such as one of those listed in Claims 18-24 (if one is appropriate),

C) a "targeting molecule" or adjuvant (if one is so desired and is appropriate).

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different antigens or pathogens, such as cholera versus anthrax (among the bacteria), or HIV versus vaccinia (among the viruses) require significantly different responses for effective immunization. The different molecular weight antigens elicit significantly different responses as the larger antigens may comprise significantly more epitopes. The different targeting molecules or adjuvants, such as cytokines or LPS, have significantly different chemical structures and function through different mechanisms. Therefore, the species of Groups I-V are independent and patentable over one another.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Applicant is advised that no references were received with the IDS form PTO-1449, received 12/29/99. Submission or resubmission of said references would expedite prosecution.

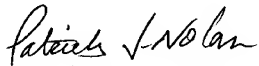
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Ewoltdt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 09/337,746
Art Unit 1644

5

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
August 6, 2001


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600